

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO:	
WAVE 3 CASES LISTED IN DEFENDANTS' EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO
DEFENDANTS' SUPPLEMENTAL MOTION TO EXCLUDE AND NOTICE OF
ADOPTION OF PRIOR DAUBERT MOTION AND REPLY OF MICHAEL THOMAS
MARGOLIS, M.D. FOR WAVE 3, AND PLAINTIFFS' NOTICE OF ADOPTION OF
MEMORANDUM IN OPPOSITION TO PRIOR DAUBERT MOTION**

Plaintiffs oppose Defendants' Supplemental Motion to Exclude for the same reasons set forth in Plaintiffs' Opposition to Defendants' Motion to Exclude Certain Opinions of Dr. Michael Thomas Margolis, M.D. for Wave 1 cases (Dkt. No. 2169), which is expressly adopted and incorporated herein by reference. The Court previously ruled on Defendants' prior motion, and in particular, denied the motion as to Dr. Margolis's opinions on complications. Dkt. 2681 at 6-7. Defendants additionally argue here that Dr. Margolis's opinions relating to the complication of degradation, and specifically degradation of mechanically cut versus laser cut mesh, are unreliable. Their criticisms of certain scientific literature and internal documents on which Dr. Margolis relies, however, go to the weight of the evidence, not its admissibility, and are appropriately addressed through cross-examination at trial. Additionally, the Court should again reject Defendants' recycled argument that scientific studies that address polypropylene do not apply to Prolene mesh. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va.

2014). Ethicon's Supplemental Motion to Exclude Certain Opinions of Dr. Margolis should be denied for these reasons as well.

ARGUMENT

I. Dr. Margolis's opinions on mechanically cut versus laser cut mesh are not unreliable under Rule 702 where he relies on Ethicon's internal documents and his own clinical experience.

Defendants seek to exclude Dr. Margolis's opinions on mechanically cut mesh (MCM) versus laser cut mesh (LCM) as unreliable, because he cites to Ethicon's internal documents and depositions in that section of his TVT and TVT-O reports. That reason alone, however, is not a basis for excluding his opinions. *Huskey*, 29 F. Supp. 3d at 722 (admitting expert opinions regarding complications of TVT-O surgical approach that were based on defendant's internal documents).

In *Huskey*, Dr. Blavais opined that the surgical approach used with the TVT-O increased the risk of certain complications. *Id.* at 722. He did not cite to any medical literature to support his opinion, but rather cited to Ethicon's internal documents, as Dr. Margolis does here. *See id.* As this Court explained, "whether an expert may rely on particular information is a different question from whether an expert's opinion has a reliable basis" under Rule 702. *Id.* Therefore, the Court concluded, "Dr. Blavais's opinions are not unreliable simply because he relied on internal Ethicon documents." *Id.*

Moreover, this is not an instance of an expert "merely parroting" the contents of Ethicon's documents, as Defendants contend. *See* Dkt. 2833 at 4. Rather, he cites to the data in support of his own experience in the field. In particular, Dr. Margolis cites to observations by Ethicon engineer, Gene Kammerer, concerning significant deformation in the MCM after it had been elongated by 50%, while the LCM suffered the same deformation issues to a lesser degree.

TVT Rep. at 17; TVT-O Rep. at 17. Dr. Margolis opines, “I personally have witnessed the same type of deformation of the mesh material, i.e., curling, roping/twisting, narrowing and fraying when I have been called upon to remove mesh months or years after implantation.” *Id.* As noted in Plaintiffs’ opposition to Defendants’ prior motion, Dr. Margolis has removed over 300 mesh or sling systems from patients suffering complications, and patients are currently referred to him from around the country at an average rate of two removal surgeries a week. Dkt. 2169 at 3.

In any event, Defendants’ challenge to the clinical significance of certain findings on which Dr. Margolis relies is misplaced. Defendants have previously raised this argument with respect to another expert’s degradation opinions. *In re: Ethicon Inc. Pelvic Repair Systems Product Liability Litig.*, No. 2327, 2016 WL 4945139, at *3 (S.D. W.Va. August 31, 2016) (denying motion to exclude on that point). Dr. Howard Jordi based certain opinions on other Ethicon studies - a Prolene suture study and an Ethicon dog study. Defendants argued that the opinions should be excluded because the studies did not assign any clinical significance to the degradation observed. *Id.* The Court summarily rejected the argument, and denied the motion on this point. *Id.*

Similarly here, to the extent Defendants take issue with Dr. Margolis’s cited data – *i.e.*, their own data – they are free to do so at trial. *See* Memorandum Opinion and Order, 8/30/16 (Dkt. 2681) at 7 (explaining with respect to Dr. Margolis’s opinions on safety and efficacy, “[t]o the extent Ethicon disagrees with this medical literature or wishes to explore nuances, its efforts are better saved for cross examination”).

II. Dr. Margolis’s other opinions on degradation are based on reliable, scientific methodology, including those based on studies relating to polypropylene mesh generally.

Defendants next argue that the scientific literature on which Dr. Margolis relies for all of his degradation opinions are unreliable, because they purportedly address polypropylene mesh generally, and not Prolene mesh specifically. The Court has previously rejected this old argument. *See Huskey*, 29 F. Supp. 3d at 703 (“It is clear that the experts in this case do not consider Prolene to be different from polypropylene for the purposes of the opinions in this case.”). Defendants’ supplemental brief adds nothing to merit a different outcome here. Defendants otherwise cherry-pick statements from the Sternschuss article and contend they are speculative. But such criticism does not render Dr. Margolis’s degradation opinions unreliable under Rule 702. If Defendants want to take issue with select statements from a single article out of context, they can argue that at trial.

First, the literature on polypropylene is not unreliable with respect to Defendants’ particular blend of polypropylene. Defendants admit that polypropylene is prone to oxidation and thus to some process of degradation. Dkt. 2833 at 6. But their contention that Prolene “is not prone to oxidation, because it contains proprietary additives” is highly disputed and misleading. *See id.* Defendants cite to select testimony of Plaintiffs’ biomaterials expert, Scott Guelcher, and seriously misconstrue it. *See id.* at 6 n.2. While Dr. Guelcher admitted that Prolene is different in that it contains antioxidants, he testified that Prolene is still prone to oxidation in the human body. He explained that the two antioxidants in Prolene work in the manufacturing process: one is designed to prevent oxidation during high-temperature processing, while the other is for storage. *Babcock*, 3/23/16 Guelcher Dep. Tr., excerpts attached as Exhibit

A, at 87:6-16. In general, such additives are known as primary and second antioxidants, respectively. *Huskey*, 8/25/14 Trial Tr., excerpts attached as Exhibit B, at 115:19-116:12.

Dr. Guelcher further explained that a foreign body reaction occurs in vivo, in which cells secrete “oxygen species that are much more reactive than molecular oxygen, so they’re much more potent. They react faster. And that [mesh] material surface is exposed to these species. So it’s exposed to these oxidizing agents.” *Huskey*, 8/25/14 Trial Tr. at 107:18-109:9. As Guelcher testified, the oxidation in vivo causes degradation, among other complications. *See Huskey*, 8/25/14 Trial Tr. at 114:16-21; *Babcock*, 3/23/16 Guelcher Dep. Tr. at 99:5-12 & 107:13-20. Significantly, he opines that the primary and secondary antioxidants that were designed to protect during processing and long-term storage are not optimized to protect polypropylene against the reactive oxygen in vivo. *Huskey*, 8/25/14 Trial Tr. at 116:15-117:24. As he states, while the antioxidants in Prolene can delay the reaction, “eventually, it’s going to happen.” *Babcock*, 3/23/16 Guelcher Dep. Tr. at 65:1-5.

The Sternschuss article on which Dr. Margolis relies is consistent with Dr. Guelcher’s testimony. The authors did not distinguish the particular constructs of the polypropylene studied, because *various* stabilizers that are added to polypropylene “are in large part responsible for the tissue responses observed after implantation....” *See Sternschuss, G., et al., Post-Implantation Alterations of Polypropylene in the Human*, J. of Urol. (2012) at 28, Ex. C to Dkt. 2169. As they say, “[t]here is no such thing as pure PP for use in medicine.” *Id.* Elsewhere in the article, the authors list various polypropylene additives, including primary antioxidants and secondary antioxidants – the very types of antioxidants found in Prolene. *See id.* at 29.

The authors also reviewed other medical literature as part of their study, including the Clavé study on which Dr. Margolis also relies regarding degradation in vivo. *See TVT Rep.* at

11 n. 8; TVT-O Rep. at 11 n.8. Dr. Guelcher relied on Clavé's study as well, and testified that it included explant mesh similar to Prolene polypropylene. *Huskey*, 8/25/14 Trial Tr. at 137:22-138:6; 188:12-23.

The totality of this evidence demonstrates that Defendants' renewed attempt to distinguish Prolene from polypropylene fails again. Defendants' motion to exclude Dr. Margolis's degradation opinions should, therefore, be denied on this point.

Second, the Sternschuss article is not otherwise speculative or unreliable as a matter of law. The authors reviewed polypropylene and medical literature regarding post-implant alterations of the material in the human body, and conclude that polypropylene is not inert in the human body. Ex. C to Dkt. 2169 at 27. They explain the oxidation of polypropylene that occurs in vivo, and recount the inflammation-degradation cycle that Dr. Margolis describes. *Id.* at 30-31. Moreover, Defendants ignore the fact that the report includes a compilation of the findings of several other researchers relating to the degradation of polypropylene in the human body, including but not limited to, the Clavé study, which "showed severe oxidative degradation of PP mesh in vivo." *See id.* at 30.

To the extent Defendants wish to challenge selective statements from the Sternschuss article, the matter is appropriately addressed at trial. *See, e.g., Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993) ("Vigorous cross examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional means of attacking shaky but admissible evidence."); Memorandum Opinion and Order, 8/30/16 (Dkt. 2681) at 7 (explaining with respect to Dr. Margolis's opinions on safety and efficacy, "[t]o the extent Ethicon disagrees with this medical literature or wishes to explore nuances, its efforts are better saved for cross examination").

In the final analysis, Dr. Margolis considered and analyzed multiple scientific articles and drew on his clinical experience to reach his opinions relating to degradation of the TVT and TVT-O mesh. Dr. Niall Galloway used this same approach in reaching his opinion that polypropylene degrades, and this Court succinctly held, “[t]his is a reliable, scientific methodology.” *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, *7 (S.D. W. Va. May 19, 2016). Defendants’ critique of Dr. Margolis’s reliance on such scientific literature goes to the weight of the evidence, not its admissibility, and Defendants’ motion should be denied for this reason as well. *See id.*

CONCLUSION

Defendants’ Supplement Motion to Exclude Certain Opinions of Michael Thomas Margolis, M.D., should be denied for the reasons set forth above, and in Plaintiff’s Opposition to Defendants’ Motion to Exclude Certain Opinions of Dr. Michael Thomas Margolis, M.D. for Wave 1 cases (Dkt. No. 2169).

Dated this 7th day of October, 2016.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 7, 2016, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Jeffrey M. Kuntz

Jeffrey M. Kuntz